UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

GILDA HAGAN-BROWN Plaintiff, v. ELI LILLY AND COMPANY, an Indiana corporation, Defendant.	CASE NO.: 1:14-CV-01614
JANINE ALI Plaintiff, v. ELI LILLY AND COMPANY, an Indiana corporation, Defendant.	CASE NO.: 1:14-CV-01615

MEMORANDUM IN OPPOSITION TO PLAINTIFF'S MOTION TO COMPEL RESPONSES TO PLAINTIFF'S REQUESTS FOR ADMISSION

Plaintiffs Janine Ali and Gilda Hagan-Brown seek to compel Defendant Eli Lilly and Company ("Lilly") to answer more fully four of Plaintiff's 61 requests for admission ("RFAs" or "requests"). Each of Plaintiff's requests, however, is fatally flawed in its form. Plaintiff has issued three requests related to issues of "cause" that properly define neither the symptoms that she seeks an admission on, rendering the request tautologous, nor the desired meaning of "cause" itself. Plaintiff also asks Lilly to admit that it is "responsible" for the Cymbalta label, a term which in her own argument she has now defined four or five separate ways. Given the complex regulatory structure in which Lilly operates, the distinction between those definitions matters. Plaintiff's reduction of Lilly's obligations under these regulations to a single word is overly simplistic and designed to prevent Lilly from referencing the fact of FDA's significant and indisputable role in the development of a medicine's label. It is not Lilly's duty to guess at what Plaintiff might mean by a request for admission or to remedy deficiencies in Plaintiff's discovery. As a result, the Court should deny Plaintiff's motion to compel.

PROCEDURAL HISTORY

Plaintiffs Ali and Hagan-Brown served identical amended sets of 61 requests for admission on February 5, 2015. *See* Plaintiff's Amended First Set of Requests for Admission ("Amended RFAs"), *Ali v. Eli Lilly & Co.*, No. 1:14-cv-01615 (Feb. 5, 2015), Ex. 1 to the Declaration of Jeffrey T. Bozman ("Bozman Decl."); Plaintiff's Amended First Set of Requests for Admission, *Hagan-Brown v. Eli Lilly & Co.*, No. 1:14-cv-01614 (Feb. 5, 2015), Bozman Decl. Ex. 2. RFAs 3, 4, and 5 asked Lilly to admit that "the abrupt discontinuation" of three different doses of Cymbalta "can cause adverse symptoms resulting from the discontinuation of CYMBALTA." Amended RFAs at 5. The term "cause" was not defined in the request. RFA 56

asked Lilly to admit "that YOU, not the FDA, bear responsibility for the content of the CYMBALTA label." *Id.* at 12. The term "responsibility" was not defined.

Lilly timely responded to Plaintiff's requests with objections, served on February 23, 2015, and responses, served on March 9, 2015. Def.'s Objections to Pl.'s Am. First Set of Requests for Admission, *Ali* (Feb. 23, 2015), Ex. 2-B to the Declaration of Brent Wisner ("Wisner Decl."), Dkt. No. 37-3; Def.'s Objections to Pl.'s Am. First Set of Requests for Admission, *Hagan-Brown* (Feb. 23, 2015), Wisner Decl. Ex. 5-B, Dkt. No. 37-3; Def.'s Resp. to Pl.'s Am. First Set of Requests for Admission, *Ali* (Mar. 9, 2015), Wisner Decl. Ex. 2-C, Dkt. No. 37-3; Def.'s Resp. to Pl.'s Am. First Set of Requests for Admission, *Hagan-Brown* (Mar. 9, 2015), Wisner Decl. Ex. 5-C, Dkt. No. 37-3. Lilly's replies to RFA 3 were thus as follows:

> Lilly objects to this Request for Admission because it is phrased as a tautology and the use of the term "cause" is vague and ambiguous as to the standard for causality. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

Def.'s Objections to Am. RFAs at 3.

> Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in some patients who are treated with Cymbalta, the abrupt discontinuation of a 30 mg/day dose of Cymbalta may be associated with certain adverse symptoms, which are listed in Cymbalta's U.S. label, but further notes that many such patients do not experience such symptoms upon discontinuation.

Def.'s Resp. to Am. RFAs at 4. Lilly provided replies that were identical other than the dose specified for RFAs 4 and 5.

Lilly objected in full to RFA 56:

> Lilly objects to this Request for Admission because its use of the term "responsibility" is vague and ambiguous. Lilly further objects to this Request to the extent that it calls for a legal conclusion.

Def.'s Objections to Am. RFAs at 21. Its responses referred Plaintiff to this objection. *See* Def.'s Resp. to Am. RFAs at 24.

Counsel for the parties met and conferred on these discovery requests, among others, on March 17, 2015, but were unable to reach agreement.

ARGUMENT

I. Legal Standard

In making requests of admission, "[t]he requesting party bears the burden of setting forth its requests simply, directly, not vaguely or ambiguously, and in such a manner that they can be answered with a simple admit or deny without an explanation, and in certain instances, permit a qualification or explanation for purposes of clarification." *Susko v. City of Weirton*, No. 5:09–CV–1, 2010 WL 1881933, at *3 (N.D.W.Va. May 7, 2010). Requests should be clear and "Rule 36 should not be used unless the statement of fact sought to be admitted is phrased so that it can be admitted or denied without explanation." *United Coal Companies v. Powell Const. Co.*, 839 F.2d 958, 967-68 (3d Cir. 1988).

II. Requests For Admission 3, 4, and 5

Plaintiff asks Lilly to admit that Cymbalta "can cause adverse symptoms resulting from the discontinuation of CYMBALTA." Amended RFAs at 5. She now glosses these requests as seeking an admission "that there is a causal connection between discontinuation and adverse symptoms." Pl.'s Mot. to Compel at 4. But as phrased in the issued written discovery, there are two deficiencies in these requests that mean they cannot be answered. Despite this, Lilly provided an answer that was responsive to the subject matter of Plaintiff's request. That Plaintiff is unhappy with the substance of this answer is no basis for a motion to compel.

First, as Lilly notes in its objections, the requests are tautological. If an adverse symptom "results from" Cymbalta discontinuation, it necessarily is "caused" by that discontinuation. If

Lilly were to admit this response as phrased, it would be entirely meaningless. The tautology is generated, in part, by Plaintiff's failure to specify about which "adverse symptoms" she seeks admissions. In apparent contradiction of the language of the requests themselves, Plaintiff argues that she is seeking an admission that that some particular, unnamed group of symptoms are causally related to discontinuation. Again, the request fails for lack of specificity. As Lilly noted in its response, its label identifies certain adverse symptoms that may be associated with discontinuation; other adverse symptoms may bear no relation whatsoever to discontinuation. The request cannot be admitted or denied as phrased.

Second, Plaintiff's request seeks an admission that Cymbalta "can cause" the unnamed symptoms subject to the request. There are differences between the legal concepts of general and specific causation -- whether a drug may cause an adverse event in any patient and whether a drug caused an adverse event in a particular patient, respectively -- and between legal and scientific causation. In scientific analysis, moreover, questions of causation are not binary and are assessed along a continuum of relatedness, rendering a single admission or denial of "cause" meaningless. As the RFAs did not define "cause" according to any standard, scale, or strength of relationship, let alone one that corresponded to an assessment of relatedness used by Lilly, Lilly objected that the term was vague and ambiguous. Def.'s Objections to Am. RFAs at 3.

While the requests could not be admitted or denied as phrased, Lilly nonetheless provided a response. Lilly stated that the abrupt discontinuation of Cymbalta may be associated with certain adverse symptoms. This association was present in clinical trial data, and although many patients did not experience these symptoms, Lilly took them seriously enough to put a warning in its label. This response therefore "fairly respond[ed] to the substance of the matter" posed in

Plaintiff's requests, Fed. R. Civ. P. 36(4), and is not an appropriate subject of a motion to compel. The Court should deny Plaintiff's attempts to obtain a revised answer.

III. Request for Admission 56

Plaintiff's RFA No. 56 is fatally vague and ambiguous in its use of the term "responsible," which is only further demonstrated by the plethora of definitions Plaintiff offers for the term in her motion. Although the RFA is, according to Plaintiff's motion, fashioned from a statement in *Wyeth v. Levine*, the RFA itself does not state that the term "responsible" is limited to its use in that case. Nor does the RFA specify that responsibility means any of "accountab[ility]," "the ability to act independently and make decisions without authorization," "legal obligation," or "moral obligation," the four definitions Plaintiff cites in her motion from English Oxford Dictionary. (Pl.'s Mot. to Compel at 6.) Furthermore, Plaintiff's motion shows that she has no intention of reading a precise definition into the term responsibility. Indeed Plaintiff's stated intention in issuing this RFA is to estop Lilly from referring to the FDA's approval of the Cymbalta label in depositions and in trial. *See* Pl.'s Mot. to Compel at 5. This is a gambit that is unjustified by the legal or factual record and should therefore be denied.

The answers to Plaintiff's RFA indeed depend on which definition of "responsibility" is being used. As *Wyeth* states, Lilly is "charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." 555 U.S. 555, 570-71 (2009). But it is subject to oversight by the FDA, which may only approve a drug after making a finding that the drug is safe and effective for use "under the conditions prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 355(b)(1)(c), (d). FDA has also continuing authority to enforce the requirement that drug labeling not be false or misleading through its ability to penalize manufacturers for distributing "misbranded" drugs, and, since 2007, to require safety labeling changes. *Id.* §§ 332-334, 352(a), 355(o)(4). As a

result, Lilly does not have "the ability to act independently and make decisions without authorizations," Pl.'s Mot. to Compel at 6, under all circumstances -- a fact recognized by *Wyeth*. *See Wyeth*, 555 U.S. at 572 (noting that there may be "clear evidence" that FDA would not approve a label change). Indeed, several more recent Supreme Court cases have clarified that *Wyeth* involved the limited situation where a company is able to use existing FDA procedures -- the so-called "changes being effected" (CBE) procedures -- to independently change its label without prior FDA approval. *See PLIVA v. Mensing*, 131 S. Ct. 2567, 2581 (2011); *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2476 (2013). As the First Circuit recently explained (in a case in which Plaintiffs' counsel here was counsel of record), "[t]he Court [in *Mensing*] thus limited *Wyeth* to situations in which the drug manufacturer can, 'of its own volition, . . . strengthen its label in compliance with its state tort duty.'" *See In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 41 (1st Cir. 2015) (quoting *Mensing*, 131 S. Ct. at 2581). Moreover, as "CBE changes rest on the existence of 'newly acquired information'" not previously analyzed by the FDA, claims alleging warning inadequacy based on information known to FDA at the time of the warning's approval are preempted under *Mensing*. *See id.* at 41-43.

There is no dispute that the information Plaintiff asserts should be in the Cymbalta label is not "newly acquired information," but data from pre-approval clinical trials duly submitted and reviewed by FDA when it first approved Cymbalta's labeling. In such a situation, not only is Lilly not free "to act independently and make decisions without authorizations" that would have the effect of "second guessing" the FDA, but in all likelihood *In re Celexa* dictates that such a claim will most likely be preempted. *See id.* at 43 (finding claims preempted where "the

change plaintiffs seek in the label is indeed based on information concerning the marginal extent of Lexapro's effectiveness that was plainly known to the FDA prior to approving the label").

In this case, the situation is even more extreme since FDA itself largely wrote the discontinuation warning for Cymbalta. As approved by the FDA in 2004, Cymbalta's labeling included a statement in the dosing section and two paragraphs in the precautions section that were written by the FDA and mandated for all antidepressants in the class, a process known as "class labeling." *See* Deposition of Sharon L. Hoog, M.D., *Hexum v. Eli Lilly and Company*, No. 13-cv-2701-SVW-MAN, at 337:2-338:1 (Dec. 10, 2014), Bozman Decl. Ex. 3; Deposition of Karen M. Becker, Ph.D., *Hexum v. Eli Lilly and Company*, No. 13-cv-2701-SVW-MAN, at 99:22-100:9, 137:7-138:1, 153:11-154:4 (Dec. 3, 2014), Bozman Decl. Ex. 4. According to FDA's guidance, "FDA will determine the appropriate content and location of a class labeling statement in [the package insert.]" Guidance for Industry: Labeling for Human Prescription Drug & Biological Products - Implementing the PLR Content and Format Requirements at 24 (Feb. 2013), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatory Information/Guidances/ucm075082.pdf. Setting aside that FDA already had the data upon which Plaintiffs base their claim here, Lilly may not change class labeling "independently" and "without authorization." *Cf.* Guidance for Industry: Safety Labeling Changes - Implementation of Section 505(o)(4) of the FD&C Act at 10 (July 2013) ("For class labeling changes, it is FDA's policy that labeling decisions should wait until all supplements and rebuttal statements submitted within 30 days of notification have been reviewed."), *available at* http://www.fda.gov/ downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm250783.pdf. Similarly, Lilly's label includes a "Highlights" section and a Medication Guide, changes to both of which require pre-approval by FDA before implementation and thus are not subject to change

through the CBE procedures on which *Wyeth* hinges. 21 C.F.R. §§ 314.70(b)(2)(v)(C); 355-1(h)(3), (h)(5)(H). Accordingly, while Lilly certainly agrees that is accountable for its product labeling, it has varying degrees of control over certain elements and changes to its label.

None of these regulatory standards should be a surprise to Plaintiff or generate the need for additional discovery, as Plaintiff alleges. *See* Pl.'s Mot. to Compel. at 8. Instead, Plaintiff states that her real intention is to "limit[] Lilly's ability to hide behind the fact that Cymbalta was 'FDA-approved' in depositions of potential witnesses and when this case is tried to a jury." *Id.* at 5. Plaintiff's fundamentally vague RFA certainly does not on its face call for any answer that would prevent Lilly's witnesses from discussing their interactions with FDA; Plaintiff's admission that this is the request's purpose only emphasizes the impossibility of requiring that Lilly admit or deny it as written. *See Susko v. City of Weirton*, No. 5:09-CV-1, 2010 WL 1881933, at *3 (N.D.W.Va. May 7, 2010). If Lilly's "responsibility," as Plaintiff uses the term in RFA 56, somehow negates FDA's more than thirty approvals of Cymbalta's label, then Lilly has no other option than to deny it. But as written, it is wholly unclear in what sense Plaintiff means "responsibility," and thus this Court should sustain Lilly's objection and deny Plaintiff's motion to compel.

CONCLUSION

For the foregoing reasons, Lilly respectfully requests that the Court deny Plaintiff's motion to compel responses to RFAs 3, 4, 5, and 56.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 1st day of April, 2015, I will electronically file the foregoing with the Clerk of Court using the CM/ECF system, which will then send a notification of such filing (NEF) to the following:

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